



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------------------------------|-------------|----------------------|----------------------------|------------------|
| 10/075,869 | 02/13/2002 | Paul D. Robbins | AP32573-AAA 072396.0237 | 9884 |
| 21003 | 7590 | 07/08/2004 | EXAMINER | |
| BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112 | | | PONNALURI, PADMASHRI | |
| ART UNIT | | PAPER NUMBER | | |
| | | 1639 | | |

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action SummaryRestriction Purpose Only

| | | | |
|-----------------|---------------------|--------------|----------------|
| Application No. | 10/075,869 | Applicant(s) | ROBBINS ET AL. |
| Examiner | Padmashri Ponnaluri | Art Unit | 1639 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1(in-part), 2, 5, drawn to a peptide having an amino acid sequence of SEQ ID NO: 76, classified in class 530, subclass 327.

Group 2. Claims 1 (in-part), 2, 5, drawn to a peptide having amino acid sequence of SEQ ID NO: 77, classified in class 530, subclass 327.

Group 3. Claims 1 (in-part), 2, 5, drawn to a peptide having amino acid sequence of SEQ ID NO: 78, classified in class 530, subclass 327.

Group 4. Claims 1 (in-part), 2, 5, drawn to a peptide having amino acid sequence of SEQ ID NO: 79, classified in class 530, subclass 327.

Group 5. Claims 1 (in-part), 2, 5, drawn to a peptide having amino acid sequence of SEQ ID NO: 80 , classified in class 530, subclass 327.

Group 6. Claims 1 (in-part), 2, 5, drawn to a peptide having amino acid sequence of SEQ ID NO: 81, classified in class 530, subclass 327.

Group 7. Claims 1 (n-part), 2, 5, drawn to a peptide having amino acid sequence of SEQ ID NO: 82, classified in class 530, subclass 327.

Group 8. Claims 1 (in-part), 2, 5, drawn to a peptide having amino acid sequence of SEQ ID NO: 83, classified in class 530, subclass 327.

Group 9. Claims 1 (in-part), 2, 5, drawn to a peptide having amino acid sequence of SEQ ID NO: 84, classified in class 530, subclass 327.

Group 10. Claims 1 (in-part), 2, 5, drawn to a peptide having amino acid sequence of SEQ ID NO: 85, classified in class 530, subclass 327.

Group 11. Claims 1 (in-part), 2, 5, and 4 drawn to a peptide having amino acid sequence of SEQ ID NO: 86, classified in class 530, subclass 327.

Group 12. Claims 1 (in-part), 2, 5, drawn to a peptide having amino acid sequence of SEQ ID Nos: 97, 98 and 99, classified in class 530, subclass 327.

Group 13. Claim 3, drawn to a peptide has the amino acid sequence of SEQ ID NO: 59, classified in class 530, subclass 327.

Group 14. Claims 6-14, 17, 42, 45-47 (in-part), drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID NO; 76 and a cargo; immunogen, classified in class 424, subclass 184.1.

Group 15. Claims 6-14, 17, 42, 45-47 (in-part), drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID NO; 77 and a cargo; immunogen, classified in class 424, subclass 184.1.

Group 16. Claims 6-14, 17, 42, 45-47 (in-part), drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID NO; 78 and a cargo; immunogen, classified in class 424, subclass 184.1.

Group 17. Claims 6-14, 17, 42, 45-47 (in-part), drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID NO; 79 and a cargo; immunogen, classified in class 424, subclass 184.1.

Group 18. Claims 6-14, 17, 42, 45-47 (in-part), drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID NO; 80 and a cargo; immunogen, classified in class 424, subclass 184.1.

Group 19. Claims 6-14, 17, 42, 45-47 (in-part), drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID NO; 81 and a cargo; immunogen, classified in class 424, subclass 184.1.

Group 20. Claims 6-14, 17, 42, 45-47 (in-part), drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID NO; 82 and a cargo; immunogen, classified in class 424, subclass 184.1.

Group 21. Claims 6-14, 17, 42, 45-47 (in-part), drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID NO; 83 and a cargo; immunogen, classified in class 424, subclass 184.1.

Group 22. Claims 6-14, 17, 42, 45-47(in-part), drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID NO; 84 and a cargo; immunogen, classified in class 424, subclass 184.1.

Group 23. Claims 6-14, 17, 42, 45-47 (in-part), drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID NO; 85 and a cargo, classified in class 424, subclass 184.1.

Group 24. Claims 6-14, 16-17, 42, 45-47 (in-part), drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID NO; 86 and a cargo; immunogen, classified in class 424, subclass 184.1.

Group 25. Claims 6-14, 17, 42, 45-47 (in-part), drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID Nos: 97-99 and a cargo; immunogen, classified in class 424, subclass 184.1.

Group 26. Claims 15, drawn to a peptide cargo complex comprising a peptide having amino acid sequence of SEQ ID NO: 59 and a cargo, classified in class 424, subclass 184.1.

Group 27. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID NO: 76; and a transfer vector, classified in class 435, subclass 320.1.

Group 28. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID NO: 77; and a transfer vector, classified in class 435, subclass 320.1.

Group 29. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID NO: 78; and a transfer vector, classified in class 435, subclass 320.1.

Group 30. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID NO: 78; and a transfer vector, classified in class 435, subclass 320.1.

Group 31. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID NO: 79; and a transfer

vector, classified in class 435, subclass 320.1.

Group 32. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID NO: 80; and a transfer vector, classified in class 435, subclass 320.1.

Group 33. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID NO: 81; and a transfer vector, classified in class 435, subclass 320.1.

Group 34. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID NO: 82; and a transfer vector, classified in class 435, subclass 320.1.

Group 35. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID NO: 83; and a transfer vector, classified in class 435, subclass 320.1.

Group 36. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID NO: 84; and a transfer vector, classified in class 435, subclass 320.1.

Group 37. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA

encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID NO: 85; and a transfer vector, classified in class 435, subclass 320.1.

Group 38. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID NO: 86; and a transfer vector, classified in class 435, subclass 320.1.

group 39. Claims 18-24 (in-part), drawn to an expression cassette comprising DNA encoding a fusion protein comprising a leader sequence, a protein of interest and an internalizing peptide having amino acid sequence of SEQ ID Nos: 97-99; and a transfer vector, classified in class 435, subclass 320.1.

Groups 40-51. Claim 25 (in-part), 31-35, drawn to a method of inducing synovial cell death comprising administering a peptide cargo complex, wherein the peptide has amino acid sequence of SEQ ID Nos 77-86 and 97-99 (NOTE each group has a different Peptide sequence), classified in class 424, subclass 184.1.

Groups 51-62. Claim 26 (in-part), 29, 31-35, drawn to a method of inducing apoptosis in a tumor cell comprising administering a peptide-cargo complex to said tumor cell, and the peptide has amino acid sequence of SEQ ID Nos: 77-86, 97-99 (NOTE each group has a different peptide sequence), classified in class 424, subclass 184.

Groups 63-74. Claim 27 (In-part), 31-35, drawn to a method for reducing white blood cells in arthritic joints comprising administering a peptide-cargo complex, wherein the peptide has amino acid sequence of Sequences 77-86 and 97-99 (Note each group is

represented by a different amino acid sequence), classified in class 424, subclass 184.1.

Groups 75-152. Claim 28 (in-part), 31-35, drawn to a method for inhibiting apoptosis in an islet cell comprising administering a peptide cargo complex to said islet cells, wherein the peptide has an amino acid sequence of SEQ ID Nos: 1-18, 25-86, 97-99 (group 148), classified in class 424, subclass 184.1.

Group 153. Claim 36-37, drawn to a method of internalizing into a peptide-cargo Complex into a cell, classified in class 424, subclass 184.1. (NOTE claim 37 is improperly dependent on claim 53).

Groups 154-165. Claims 38-41 (in-part), drawn to a method of internalizing a peptide-cargo complex into a cell comprising administering a peptide-cargo complex, and a GST-fusion protein, a glutathione as cargo, and the peptide has amino acid sequence of SEQ ID Nos: 76-86 and 97-99classified in class 424, subclass 184.1.

Groups 166-177. Claims 48-50, drawn to a method for eliciting an immune response in a subject comprising administering an immunogen comprising a peptide-cargo complex, wherein the peptide has amino acid sequence of SEQ ID Nos: 76-86 and 97-99, classified in class 424, subclass 184.1.

Groups 178-189. Claims 30, 34-35, drawn to a method for delivering anti-oxidant and anti-inflammatory agents to lung epithelial cells by administering a peptide-cargo complex, wherein the peptide has amino acid sequence of SEQ ID Nos: 76-86 and 97-99, classified in class 424, subclass 184.1.

[NOTE that in all the groups sequence ID Nos: 97-99 are grouped as a single group because they all share a common core structure RRQRR].

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of groups 1 and 13 are drawn to distinct peptides with different amino acid sequences. The peptides are structurally distinct, and do not share a common core structure.

Thus the restriction between the groups is proper.

3. Inventions of groups 14-26 are all drawn to different peptide-cargo complexes each with a different peptide sequence. The peptide sequences are structurally distinct and are not capable of use together.

4. Inventions of groups 27-39 are drawn to different expression cassettes with different peptide sequences. The different peptide sequences are structurally distinct from each other and are not capable of use together.

5. Inventions of groups 1-13 (peptides), 14-26 (peptide-cargo complexes), 27-39 (expression cassette) are distinct from each other and are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Thus, restriction between the groups is proper.

6. Inventions of groups 40-189 are all drawn to different methods using different peptide-cargo complexes. The different methods of groups 40-189 are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Thus, restriction between the groups is proper.

7. Inventions of groups 14-26 (products) and groups 40-189 (methods) are related as product and process of use. The inventions can be shown to be distinct if either or both of the

following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the different products of groups 14-26 can be used in more than one group of groups 40-189. Thus restriction between the groups is proper.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

A. If either groups 14-26 or 40-189 are elected applicants are requested to elect a single specific species of cargo; and if the cargo is apoptotic protein the sequence of apoptotic protein in claim 33.

B. If either groups 27-39 are elected, applicants are requested to elect a single species of a) leader sequence; b) a protein of interest.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639



PADMASHRI PONNALURI
PRIMARY EXAMINER